REMARKS/ARGUMENTS

Claims 1, 6, 8-21, 25-43 and 45-61 are under examination in the application. Claims 4, 5, 7, 22-24, 44 and 62-80 have been cancelled. The Final Office Action mailed on July 2, 2007 includes the following rejections:

1. Claims 1, 5-22, 24-43 and 45-61 are rejected under 35 U.S.C. § 103(a).

Claim Rejections – Claims 1, 5-22, 24-43 and 45-61are rejected under 35 U.S.C. § 103(a)

The Action rejects claims 1, 5-22, 24-43 and 45-61 under 35 U.S.C. § 103(a) as being unpatentable over Devane, et al., U.S. Patent No. 6,228,398 (Devane), in view of Dang, et al., U.S. Patent No. 6,462,094 (Dang) and U.S. Patent Application No. 2003/0049318 (Davis).

Applicants submit that the combination of references fail to teach every element of the present invention. Specifically, the combination of Devane and Dang do not teach an enveloped pharmaceutical composition having a first active available for immediate release, wherein over 80% of the first active disposed on a carrier and is released within 60 minutes; and a second active is disposed on a bead for extended release and an extended release coating. The second active includes three or more layers of the second active agent and wherein over 80% of the second active is released between 90 minutes and 6 hours.

The combination of references does not teach the active agents being on separate carriers. The combination of references does not teach the use of an extended release coating AND an extended release matrix (i.e., bead). The combination of references does not teach the addition of three or more layers on the second active agent.

Furthermore, Applicants traverse the statement made in the Action at page 3 that "[u]sing traditional spray-coating, there is not was to apply exactly "three or more layers"." The skilled artisan knows that each time that a spray-coating event is conducted on a pharmaceutical product that a single layer is being added to the target pharmaceutical. In fact, the skilled artisan knows not only the number of layers added to the target pharmaceutical but the exact thickness of each, within well-known parameters. Furthermore, the regulatory requirements of agencies like the USDA and the FDA have stringent controls over the thickness, stability and release profiles that are achieved during the manufacturing process.

Accordingly, Applicants respectfully submit that claims 1, 6, 8-21, 25-43 and 45-61 are not obvious over Devane, Dang and Davis, therefore, allowable under 35 U.S.C. § 103(a). For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 103.

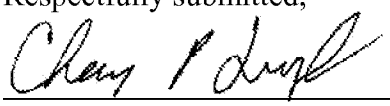
Conclusion

Accordingly, after entry of this Amendment, the claims numbering has been corrected, original Claims 1, 6, 8-21, 25-43 and 45-61 are pending in the above-identified Application. Withdrawal of the objections and rejections and an early Notice of Allowance are earnestly requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Dated: December 3, 2007.

Respectfully submitted,



Chainey P. Singleton
Reg. No. 53,598
ATTORNEY FOR APPLICANTS

Customer No. 34,725
Chalker Flores, LLP
2711 LBJ FRWY, Ste. 1036
Dallas, TX 75234
214.866.0001 Telephone
214.866.0010 Facsimile